Section 5
510(k) Summary
[As required by 21 CFR 807.92]

AUG 16 2013

1. Submission Information:

510(k) Number:	K123830
Date:	June 26th, 2013
Type of 510(k) Submission:	Traditional
Basis for 510(k) Submission:	New device
Submitter/Manufacturer:	Dalian Labtek Science & Development Co., Ltd. 2-2-2-2, No.4 Zhengren Street, Shahekou District, Dalian, China 116021
Contactor:	Doris Dong, Consultant Shanghai CV Technology Co., Ltd. Room 1706, No. 128 Songle Rd., Songjiang Area, Shanghai, China 201600 E-mail: doris_d@126.com / Url: www.ceve.org.cn Tel: 86 21-31261348 / Fax: 86 21-37824346

2. Device Description:

Proprietary Name:	Veinoflow SCD, Model LBTK-M-I 5001
Common Name:	Intermittent Pneumatic Compression Device
Classification Name:	Compressible limb sleeve
Regulation Number:	21 CFR 870.5800
Product Code:	JOW
Device Class:	II
Review Panel:	Cardiovascular
Indications for use:	Veinoflow SCD system, Model LBTK-M-I 5001 is a system to prevent DVT (Deep Vein Thrombosis) by improving the blood velocity of patients. LBTK-M-I 5001 is indicated for Circulation Enhancement, Deep Vein Thrombosis Prophylaxis, Edema -Acute, Edema - Chronic, Extremity Pain Incident to Trauma or Surgery, Leg ulcers, Venous Stasis / Venous Insufficiency.
Device Description:	***1) Description of the compression system*** Veinoflow SCD, Model LBTK-M-I 5001, is a pneumatic pump system that supplies compressed air to inflate garments that are attached to a patent's lower limbs. It consists of a pump controller, specially designed inflation and deflation garments for feet and legs, air supply tubes, and power line. The inflation and deflation garments have 3 types: ① thigh-calf garments, ② calf garments, and ③ foot cuffs. The system offers sequential inflation and propels the vein blood from limb to heart, therefore enhance the blood circulation. The controller can automatically detect the external garment type, and provides pressure correspondingly. The pressure value and inflatable interval time are preset and adjustable. The controller has a self test system, when there is any error, it will alarm both in visual and audio.

	All the thigh-calf garments, calf garments and foot cuffs are packaged in pairs. The controller can function properly in both situations either when connected to a one single thigh-calf garment/calf garment/foot cuff or one pair of thigh-calf garments/calf garments/foot cuffs, giving the end user more flexibility for prophylaxis options. ***2) Description of the thigh-calf garments, calf garments and foot cuffs*** The thigh-calf garments, calf garments and foot cuffs of Veinoflow SCD, LBTK-M-I 5001, are constructed of four layers, two layers of non-laminated PVC welded together to form bladders with covers made from non-woven fabric, which form a "pillowcase" around the bladders. The tubing is welded into the bladders, beneath the sleeves. Each thigh-calf garment or calf garment has 3 bladders, while each foot cuff has 1 bladder. The proposed single-patient-use, disposable thigh-calf garments, calf garments and foot cuffs are biocompatible. ***3) Description of tubing*** The material of air tubing is PVC (polyvinyl chloride). The material of tubing plug and connector is ABS (acrylonitrile butadiene styrene plastic). Each set of tubing is 2m long. The material of the air tube connector in garments/cuffs is TPU (thermoplastic polyurethane elastomer), while the material of the plug is ABS.
Product Validation Testing	1) Pressure testing 2) Inflation/deflation time 3) Anti-stretch test of garment materials 4) Anti-stretch test of air chamber welding point 5) Air leakage test 6) Burst testing of garment 7) Bladder fatiguing test 8) Velcro adhesion evaluation test 9) Biological compatibility test 10) Electromagnetic compatibility test 11) Electrical Safety test
Standards:	ISO 10993-1: 2009: Evaluation and testing within a risk management process ISO 10993-5: 2009: Tests for cytotoxicity: In vitro methods; ISO 10993-10: 2010: Tests for Irritation and Sensitization; IEC 60601-1: 2005: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

3. Substantial Equivalence:

Detailed comparison data is included in the section 9 of "Substantial Equivalence Discussion" of this 510(k) submission.

	New Device	Predicate Device
510(k) Number:	K123830	K112677
Product Code:	JOW	JOW
Proprietary Name:	Veinoflow SCD, LBTK-M-I 5001	The Venous Assist System DVT-2600
Manufacturer:	Dalian Labtek Science & Development Co., Ltd.	DAESUNG MAREF CO LTD
Indications for use:	Veinoflow SCD system, Model LBTK-M-I 5001 is a system to prevent DVT (Deep Vein Thrombosis) by improving the blood velocity of patients. LBTK-M-I 5001 is indicated for Circulation Enhancement, Deep Vein Thrombosis Prophylaxis, Edema -Acute, Edema - Chronic, Extremity Pain Incident to Trauma or Surgery, Leg ulcers, Venous Stasis / Venous Insufficiency.	DVT-2600 is a system to prevent DVT (Deep Vein Thrombosis) by improving the blood velocity of patients. DVT-2600 is indicated for Circulation Enhancement, Deep Vein Thrombosis Prophylaxis, Edema -Acute, Edema - Chronic, Extremity Pain Incident to Trauma or Surgery, Leg ulcers, Venous Stasis / Venous Insufficiency.
Components:	pump controller, multi-cavity thigh-calf garments, calf garments, foot cuffs, battery, air supply tubes, power line	pump controller, multi-cavity thigh-calf garments, calf garments, foot cuffs, battery, air supply tubes, power line
Ingress of Water Protection	Ordinary	Ordinary
Compression Type	Thigh-calf garments & calf garments: Sequential, Gradient Foot Cuffs: Uniform	Thigh-calf garments & calf garments: Sequential, Gradient Foot Cuffs: Uniform
Compression time	Single thigh-calf garment: 5.5s Compression Dual thigh-calf garments: 11s Compression Single calf garment: 4s Compression Dual calf garments: 8s Compression Single foot cuff: 2.5s Compression Dual foot cuffs: 5s Compression	Single thigh-calf garment: 5.5s Compression Dual thigh-calf garments: 11s Compression Single calf garment: 4s Compression Dual calf garments: 8s Compression Single foot cuff: 2.5s Compression Dual foot cuffs: 5s Compression
Deflation time	2~3s	2~3s
Default inflatable interval time	48s	48s
Adjustable inflatable interval time	24s, 48s, 60s	24s, 48s, 60s
Default Pressure	Thigh-calf garments & calf garments: 40 mmHg Foot Cuffs: 130 mmHg	Thigh-calf garments & calf garments: 40 mmHg Foot Cuffs: 120 mmHg
Adjustable pressure	Thigh-calf garments & calf garments: 30~60mmHg	Thigh-calf garments & calf garments: 20~60mmHg

	Foot Cuffs: 120~140mmHg	Foot Cuffs: 120~140mmHg
Mode of Operation	Continuous	Continuous
Application mode	① Single thigh-calf garment Compression; ② Dual thigh-calf garments Compression; ③ Single calf garment Compression; ④ Dual calf garments Compression; ⑤ Single Foot cuff Compression; ⑥ Dual Foot cuffs Compression; ⑦ Simultaneous single thigh-calf garment and single calf garment Compression	① Single thigh-calf garment Compression; ② Dual thigh-calf garments Compression; ③ Single calf garment Compression; ④ Dual calf garments Compression; ⑤ Single Foot cuff Compression; ⑥ Dual Foot cuffs Compression; ⑦ Simultaneous single thigh-calf garment and single calf garment Compression; ⑧ Simultaneous single foot cuff and single thigh-calf garment Compression; ⑨ Simultaneous single foot cuff and single calf garment Compression
Bed Hook	Yes	Yes
Power Cord Storage	Yes	Yes
Audible/Visual Alarms	No garment, Pump Error, Valve Error, Temperature Error, Software Error, System Error, High Pressure, Low Pressure, Low Battery	Cuff connection Error, Pressure Error, System Error, Power Error
Controller Dimensions	Length: 240mm; Width: 140mm; Height: 263mm	Length: 205mm; Width: 155mm; Height: 195mm
Controller Weight	3.5kg	1.9kg
Power Requirement	AC 100-240V, 50VA, 50/60 Hz	AC 100-240V, 35VA, 50/60 Hz
Battery	14.8V, 3100mAhr, Lithium Ion (Optional) Run Time: 3-4 hours Charge Time: 4~5 hours (charging only)	11.1V, 2500mAhr, Lithium Ion (Optional) Run Time: 6-8 hours Charge Time: 4 hours (charging only)
Shoulder Strap	Yes (optional)	Yes
Shipping Unit	Each	Each
Standards:	ISO 10993-1, ISO 10993-5, ISO 10993-10, IEC 60601-1, and IEC 60601-1-2	ISO 10993-1, ISO 10993-5, ISO 10993-10, IEC 60601-1, and IEC 60601-1-2
Validation testing:	1) Pressure testing; 2) Inflation/deflation time	1) Biological compatibility test

	3) Anti-stretch test of garment materials 4) Anti-stretch test of air chamber welding point 5) Air leakage test; 6) Burst testing of garment; 7) Bladder fatiguing test; 8) Velcro adhesion evaluation test; 9) Biological compatibility test; 10) Electromagnetic compatibility test; 11) Electrical Safety test	2) Electromagnetic compatibility test 3) Electrical Safety test
Non-sterile:	Non-sterile	Non-sterile
Microprocessor Control?	Yes	Yes
Differences:	The new device and the predicate device have different Audible/Visual Alarms, dimensions and weight, battery capacity, and LCD display panel. The new device has more safety testing on thigh-calf garments, calf garments and foot cuffs.	
Similarities:	The new device and the predicate device, both are portable, equipped with battery, have same intended use, components, function, working principle, operation mode, compression type, power supply, same compression cycle and similar preset pressure values, and similar conformity standards.	
Conclusion:	Since the new device has same components, working principle, intended use, and safety features with the predicate device, they are substantial equivalent. Though the two devices have slightly differences, for example, different default pressure for foot cuffs, however, the new device can be adjusted to the same pressure as the predicate device. And the adjustable pressure range for foot cuffs is same. In addition, the adjustable pressure range for thigh-calf garments/calf garments of the new device is different from the predicate device, however, it is covered by the adjustable pressure range of the predicate device. Except that single foot cuff can not be used with single thigh-calf garments/calf garment simultaneously, the new device and the predicate device has same application mode of garments/cuffs. Any difference in technological characteristics does not raise any new safety and effectiveness issues. The conclusion drawn from the testing (Electrical Safety test, Pressure testing, Inflation/deflation time, Air leakage test, Burst testing, and so on) is that the device is substantially equivalent to the predicate device.	

4. Discussion of Substantial Equivalence to the Predicate Device

Veinoflow SCD system is a non-invasive medical device that delivers air to the garments and sequentially pressures them. Accordingly, the Veinoflow SCD system is intrinsically safe. Apart from the intrinsic safety of the physiological mechanism of the Veinoflow SCD system, the product components are designed to minimize potential risks to patients during product use. In particular, the product is equipped with the following safety features:

① Audio and visual alarms are activated if inflation garments pressure either exceeds or fails to achieve recommended levels.

② Relevant contraindications, numerous warnings concerning proper use and maintenance, are contained in the instruction manual.

③ The product labeling indicates that the device is restricted to sale by or on the order of a physician.

④ Software validation and other safety features.

The Veinoflow SCD, Model LBTK-M-I 5001, has passed biocompatibility safety, electricity safety and electromagnetic compatibility safety testing according to:

ISO 10993-1: 2009: Evaluation and testing within a risk management process

ISO 10993-5: 2009: Tests for cytotoxicity: In vitro methods;

ISO 10993-10: 2010: Tests for Irritation and Sensitization;

IEC 60601-1: 2005: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

Moreover, the garments of the device and the whole system passed bench testing of: Pressure testing, Inflation/deflation time, Anti-stretch test of garment materials, Anti-stretch test of air chamber welding point, Air leakage test, Burst testing of garment, Bladder fatiguing test, and Velcro adhesion evaluation test.

Veinoflow SCD system, Model LBTK-M-I 5001 has the same technological characteristics, intend use, design, function, composition and mode of operation to the predicate device.

The conclusion drawn from the bench testing is that the device is substantially equivalent to the predicate device. Furthermore, the device complies with the recognized standards and performs its intended tasks as well as the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 16, 2013

Dalian Labtek Science & Development Co., Ltd.
c/o Doris Dong
Consultant
Shanghai CV Technology Co., Ltd.
Room 1706, No. 128 Songle Rd., Songjiang Area
Shanghai, China 201600

Re: K123830
Trade/Device Name: Veinoflow SCD, Model LBTK-M-I 5001
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: June 27, 2013
Received: July 16, 2013

Dear Ms. Dong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4
Indications for Use

510(k) Number (if known): K123830

Device Name: Veinoflow SCD, Model LBTK-M-I 5001

Indications for Use:
Veinoflow SCD system, Model LBTK-M-I 5001 is a system to prevent DVT (Deep Vein Thrombosis) by improving the blood velocity of patients. LBTK-M-I 5001 is indicated for Circulation Enhancement, Deep Vein Thrombosis Prophylaxis, Edema -Acute, Edema - Chronic, Extremity Pain Incident to Trauma or Surgery, Leg ulcers, Venous Stasis / Venous Insufficiency.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)